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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,432	02/08/2002	Phyllis B. Siegel	1050-5	3909

7590

03/12/2003

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EXAMINER

CARRILLO, BIBI SHARIDAN

ART UNIT

PAPER NUMBER

1746

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/072,432

Applicant(s)

SIEGEL ET AL.

Examiner

Sharidan Carrillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7, 16 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4, 7, 16 and 29-32 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 7 and 16, drawn to a method of cleaning a medical unit water line, classified in class 134, subclass 22.1.

II. Claims 25-32, drawn to a composition, classified in class 510, subclass 161.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as in dishwashing or a food processing plant.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Mr. John Lezdey on 3/6/03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-4, 7 and 16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Priority***

4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after

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November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

5. Applicant claims priority to 09/608,048, filed 6/30/2000. The '048 application is directed to "Flow control subsystem for a fuel cell system". This Serial No. is incorrect. Priority should be claimed to U.S. 09/608,046, filed 6/30/2000, now abandoned.

*Specification*

6. The amendment filed 2/8/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Amendments to the Summary of the Invention, Page 1, second paragraph, and Amendments made to Page 9, line 11. It is noted that these Amendments to the Specification were made to support new claims 25-32. However, such amendments to the specification constitute new matter, the limitations of which are not supported by the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide proper antecedent basis for the limitations of claim 2 and the negative limitation of "wherein the solution contains no horse radish peroxidase.

*Claim Rejections - 35 USC § 112*

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sodium or potassium salt of iodide, citric acid as an

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organic acid, and the oxidizing agents, as recited in claim 7, does not reasonably provide enablement for any iodide salt, any organic acid, and any oxidizing agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims embrace an invention which contains any known iodide salt, any known organic acid, and any known oxidizing agent, which could/can be selected from literally thousands. It does not appear to be feasible that any iodide salt, any known organic acid, and any known oxidizing agent would function in the present invention. Further, for one skilled in the art to reproduce the present invention (which must be possible, if the specification is adequate), there would clearly be undue experimentation to do so in an attempt to figure out which iodide salts, organic acids, and oxidizing agents would work and which ones would not.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-4, 7, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 16 are indefinite because it is unclear what one of ordinary skill in the art would consider as a “naturally acquired” biofilm. Claims 1 and 16 are further indefinite because it is unclear what one of ordinary skill in the art would consider as a “sufficient period”. Claim 2 is indefinite because it is unclear whether this step is performed prior to, or following the cleaning of the medical water line. Claims 3-4 are indefinite because of its dependency. In claim 7, the examiner suggests using the terminology, “selected from the group consisting of”.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 4, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Rabon et al. (US2002/0173437 A1).

Rabon et al. teach a method for cleaning medical equipment or dental equipment, such as tubing to remove microorganisms and bacteria. In reference to claim 1, Rabon et al. teaches an iodide salt (i.e. paragraph 167, ammonium salts of iodide), an organic acid (citric acid, paragraph 80), and oxidizing agents (ie. sodium perborate, hydrogen peroxide, paragraph 110). In paragraphs 29, 30, 57, and 182, Rabon et al. teach washing and rinsing the equipment. Also refer to claim 17 of Rabon et al. which further teaches washing, followed by a rinsing step. In reference to claim 4, refer to paragraph 15. In reference to claim 7, refer to paragraph 110.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 2,3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabon et al. (US2002/0173437A1).

Rabon et al. teach cleaning tubing used in dental equipment, as previously discussed. Rabon et al. fail to teach the limitations of claim 2. However, in view of the indefiniteness as previously discussed above, it would have been within the level of the skilled artisan to have been modified the method of Rabon et al. to clean tubing which have been exposed to human saliva since saliva is in contact with tubing during normal use in a dentist's office and requires cleaning prior to being reused.

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In reference to claim 3, Rabon et al. fail to teach the diameters of the tubing. However, Rabon et al. teach cleaning tubing used in dental and medical equipment. In the absence of a showing of criticality, it would have been within the level of the skilled artisan to clean tubing having small diameters since Rabon et al teach cleaning tubing used in dental equipment, wherein such tubings have small diameters.

***Allowable Subject Matter***

17. Claim 16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

18. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to teach the limitations of claim 16, specifically, the prior art fails to teach removing biofilm from a medical unit water line using a composition comprising approximately 0.25 g sodium iodide, 1.6 g citric acid, 0.8 g sodium persulfate, 0.03 g sodium percarbonate dissolved in 1 liter of water, wherein the solution contains no horseradish peroxidase.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Oldenhove teaches a cleaning composition for disinfecting. Johansen teaches a method for enzymatic treatment of biofilm. Goldstein et al. teach a method of cleaning dental equipment. Johansen et al. a method of cleaning hard surfaces. Tarara et al. teach an enzyme cleaning composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharidan Carrillo whose telephone number is 703-308-1876. The examiner can normally be reached on Monday-Friday, 6:00a.m-2:30pm.

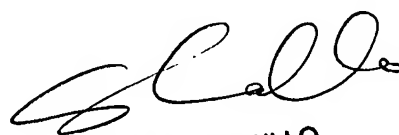
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on 703-308-4333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7719 for regular communications and 703-305-7719 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Sharidan Carrillo  
Primary Examiner  
Art Unit 1746

bsc  
March 7, 2003

A handwritten signature in black ink, appearing to read 'Sharidan Carrillo', written in a cursive style.

**SHARIDAN CARRILLO  
PRIMARY EXAMINER**